UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	)	MDL NO. 1456
	)	CIVIL ACTION: 01-CV-12257-PBS
	)	Judge Patti B. Saris
THIS DOCUMENT RELATES TO *U.S. ex rel. Ven-A-Care of the Florida Keys, Inc., Zachary T. Bentley, and T. Mark Jones v. Abbott Laboratories, Inc.*, No. 07-CV-11618-PBS	)	Magistrate Judge Marianne B. Bowler

ABBOTT LABORATORIES, INC.'S REPLY IN SUPPORT OF REQUEST FOR CERTIFICATION OF INTERLOCUTORY APPEAL UNDER 28 U.S.C. § 1292(B) AND STAY OF DISCOVERY PENDING APPEAL

This Court should certify for interlocutory review its March 14, 2008 order denying Abbott's motion to dismiss Ven-A-Care's False Claims Act complaint for lack of jurisdiction under the Act's first-to-file bar, 31 U.S.C. § 3730(b)(5). All the requirements for certification are amply satisfied here:

- the order involves subject-matter jurisdiction, which is a controlling question of law;
- there is "substantial ground for difference of opinion" with the Court's order, *i.e.*, whether a second-filed complaint alleging different transactions that are part of the same scheme is invalid under the first-to-file bar; and
- immediate appeal will "materially advance the ultimate termination" of this litigation. Indeed, reversal would terminate the case.

Ven-A-Care fails to provide any legitimate opposition on these points. Instead, it tries to claim, implausibly, that the scheme alleged in the DOJ complaint case was narrow, but then claims that the present case is so similar that it could be tried with the DOJ case, with minimal additional discovery. All the while, Ven-A-Care never provides case law that supports its positions. Abbott's motion should be granted, and discovery should be stayed pending appeal to prevent the waste of resources that would entail if the First Circuit grants review and reverses.

I. THE COURT'S MARCH 14, 2008 ORDER UNDISPUTEDLY INVOLVES A CONTROLLING QUESTION OF LAW AND IS PARTICULARLY APPROPRIATE FOR INTERLOCUTORY APPEAL IN THIS CIRCUIT.

Ven-A-Care does not contest that an order denying dismissal based on subject matter jurisdictional grounds involves a controlling question of law. Instead, Ven-A-Care offers the over-broad assertion that "[a]s a general rule, the First Circuit does not grant interlocutory appeals from the denial of a motion to dismiss." (Opp. at 2.) But that assertion misses the point. It is black-letter law that, whether issued on a motion to dismiss or otherwise, orders rejecting challenges to subject matter jurisdiction – like this Court's March 14, 2008 order – are obviously suited for interlocutory appeal within the general criteria of Section 1292(b). (Mot. at 4.) The First Circuit regularly accepts interlocutory appeals from such orders, regardless of the nature of the motion prompting them,[1] and indeed, Ven-A-Care cites *not a single case* where the First Circuit denied an interlocutory appeal of an order finding subject-matter jurisdiction, simply because the issue was raised as a motion to dismiss.[2]

II. THERE IS A SUBSTANTIAL GROUND FOR DIFFERENCE OF OPINION JUSTIFYING INTERLOCUTORY APPEAL.

Ven-A-Care next argues that there is no ground for difference of opinion with this Court's ruling. As Abbott's motion showed, that is demonstrably false. While the ruling is

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[1] *See Marquis v. FDIC*, 965 F.2d 1148, 1150-51 (1st Cir. 1992) (accepting interlocutory appeal of denial of motion to dismiss for lack of subject matter jurisdiction); *United States v. Puerto Rico*, 721 F.2d 832, 833 (1st Cir. 1983) (Selya, J.) (same); *Rodriguez v. Am. Int'l Ins. Co. of P.R.*, 402 F.3d 45, 46 (1st Cir. 2005) (accepting interlocutory appeal from summary judgment order finding subject-matter jurisdiction); *United States v. Lahey Clinic Hosp., Inc.*, 399 F.3d 1, 4 (1st Cir. 2005) (accepting interlocutory appeal of court order finding subject-matter jurisdiction, raised in motion for "judgment on the pleadings and, in the alternative, for summary judgment"); *cf. S.G. v. Am. Nat'l Red Cross*, 938 F.2d 1494, 1495-96 (1st Cir. 1991) (accepting interlocutory appeal denial of motion to remand for lack of federal subject matter jurisdiction), *rev'd on substantive grounds*, 505 U.S. 247 (1992).

[2] One case cited by Ven-A-Care, *Caraballo-Seda v. Municipality of Hormigueros*, 395 F.3d 7, 9 (1st Cir. 2005), involved the rejection of an interlocutory, subject-matter jurisdiction appeal raised at the motion-to-dismiss stage. In that case, however, the First Circuit *did* originally accept the interlocutory appeal, but later dismissed it as improvidently granted because the Court found that two prongs of the § 1292(b) test were not satisfied: (1) that there was no "substantial ground for difference of opinion" on issue, with all prior courts having reached the same decision; and (2) that a decision would not have "materially advance[d] the ultimate termination of the litigation" because other claims in the same case were still proceeding in the district court. *Id.* That obviously is not this case.

succinct ("Denied on the ground that the [DOJ] complaint does not make allegations related to Erythromycin"), there is a substantial ground for a difference of opinion under any reasonable interpretation of that ruling.

First, the Court's order could be viewed as imposing an "identical facts" requirement, in which case there absolutely would be a substantial ground for difference of opinion, as every federal circuit court to address the first-to-file bar has rejected such a test. (Mot. at 5-6.) Indeed, Ven-A-Care agrees that, were this the Court's rationale, there would be a substantial ground for difference of opinion. (Opp. at 4.)

Second, to the extent that the Court was applying some legal metric other than the "identical facts" test, the order's result would still leave substantial grounds for disagreement. (Mot. at 6-7.) In at least three other decisions, courts have applied the first-to-file bar to strikingly similar facts: *i.e.*, a first-filed complaint alleging a broad-based fraudulent scheme without specifically identifying all of the fraudulent conduct encompassing that scheme and a second-filed complaint alleging the same scheme, that merely identifies additional fraudulent transactions.[3]

Ven-A-Care's response—that the first-filed DOJ complaint cannot bar the Massachusetts complaint because the DOJ case involved "different drugs sold by different people to a different market segment," and thus "nothing alleged . . . in the intervened [DOJ] case would have alerted the federal government about the fraud emanating from Abbott's PPD division" (Opp. at 4)—is as legally unsupported as it is factually incorrect.

[3] *United States ex rel. Hampton v. Columbia/HCA Healthcare Corp.*, 318 F.3d 214, 218-19 (D.C. Cir. 2003); *United States ex rel. LaCorte v. SmithKline Beecham Clinical Labs, Inc.*, 149 F.3d 227, 233 (3d Cir. 1998); *United States ex rel. Tillson v. Lockheed Martin Energy Sys., Inc.*, No. 5:00CV-39-M, 2004 WL 2403114, at *9 (W.D. Ky. Sept. 30, 2004).

On the law, other courts generally agree that a mere recitation of "different facts" is insufficient to avoid the first-to-file bar, so long as it involves the same fraudulent *scheme*. *United States ex rel. Lujan v. Hughes Aircraft Co.*, 243 F.3d 1181, 1189 (9th Cir. 2001) (holding that first-to-file bar is implicated where a later-filed *qui tam* contains "the same *material elements* of fraud described in an earlier suit, regardless of whether the allegations incorporate somewhat different details.") (emphasis added); *LaCorte*, 149 F.3d at 232-33; (first-to-file bar implicated by subsequent suit "alleging the same elements of a fraud"); *Hampton*, 318 F.3d 214, 217-18 (D.C. Cir. 2003) (rejecting later-filed complaint that contained "merely variations on the fraud [the first-filed] complaint described"). Here, the scheme alleged in the two complaints are identical: that Abbott reported allegedly inflated pharmaceutical prices to sources that Medicare relied upon to set reimbursement rates for Abbott products. Ven-A-Care itself affirmatively stated this when moving to transfer this case to the MDL. (Dkt. No. 4861 Ex. P at 2.)

On the facts, Ven-A-Care's attempt to minimize the allegations of the DOJ complaint, claiming that they covered only infusion drugs sold by one Abbott division, cannot be taken at face value. That first-filed complaint explicitly stated that Abbott's alleged pricing scheme was broader than the drugs and transactions identified in the complaint, and sought damages for "all pharmaceuticals of all sizes . . . about which false price and cost representations" were made. (*See id.* at 8). And, despite Ven-A-Care's suggestion to the contrary, that first-filed complaint did, at one point, include Erythromycin claims, *including several of the NDCs at issue here*. (*See id.* at 7-8.) In light of its own prior actions, Ven-A-Care cannot now legitimately claim that the first-filed complaint did not cover, and could not have covered, Erythromycin claims. Nor has Ven-A-Care ever given any reasoned explanation to support its contention that the Government lacked the capacity to learn of Abbott's alleged mis-pricing of Erythromycin based on the

information provided in the first-filed complaint, given that: (1) the "scheme" was uncovered by comparing published prices with "sale" prices; (2) the published prices were public; and (3) the Government had several methods at its disposal to learn of the "sale" prices from third-parties or from Abbott itself.[4]

Moreover, Ven-A-Care's attempted factual distinctions are irrelevant and only highlight the substantial ground for difference of opinion. Indeed, despite those attempt to distinguish the case law, Ven-A-Care still begrudgingly admits that case law *does* exist in other jurisdictions applying the first-to-file bar where the barred complaint identified different "divisions" and transactions. (Opp. at 6 (recognizing that in *Hampton*, "the second complaint did mention fraudulent transactions at a home health agency in a state not mentioned in the first.")); *see also United States ex rel. Capella v. United Techs. Corp.*, No. 3:94-CV-2063, 1999 WL 464536, at *9 (D. Conn. June 3, 1999) (holding that "section 3730(b)(5) precludes a subsequent relator's claim that alleges the defendant engaged in the same type of wrongdoing as that claimed in a prior action, even if the allegations cover a different time period *or location within a company*") (emphasis added; cited in Opp. at 4).[5] That Ven-A-Care disputes these courts' reasoning only reinforces Abbott's argument that the Court's order on this issue should be certified for interlocutory appeal.

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[4] *See, e.g.*, 31 U.S.C. § 3733(a)(1) (giving DOJ power to issue civil investigative demands to "any person [who] may be in possession, custody, or control of any documentary material or information relevant to a false claims law investigation"); 5 U.S.C. app. 3 §§ 1, 4, 6(a)(4), 11 (giving Inspector General of HHS the power to "to require by subpena [sic] the production of all information, documents, reports, answers, records, accounts, papers, and other data and documentary evidence necessary" to investigate HHS programs such as Medicaid). Indeed, given the decades of government reports discussing the disparity between AWP and "true" prices, it is undeniable that the Government had access to factual information about "true" prices without Ven-A-Care's help.

[5] Ven-A-Care again complaints that Abbott tried to limit discovery in the DOJ case to the drugs specifically being litigated by the Government, which do not include Erythromycin. (Opp. at 4.) But the fact that Abbott has urged, and the Court has agreed, that discovery in the DOJ case be limited to the specific drugs that the Government chose to pursue (as well as certain cross-cutting evidence) is wholly irrelevant to the question of whether the *allegations* of the first-filed and subsequent-filed complaints are related.

III. AN INTERLOCUTORY APPEAL WILL "MATERIALLY ADVANCE THE TERMINATION OF THE LITIGATION" HERE.

Finally, Ven-A-Care does not dispute that, if an appeal were allowed and this Court's order were reversed, the case would immediately end – thus unquestionably and materially advancing the termination of the litigation. And while Ven-A-Care asserts that, if this case goes forward, it could (absent a stay) "be readied for trial with relatively little additional discovery and in tandem with the [DOJ's] case against Abbott" (Opp. at 6-7), that is patently false:

- The cases are on very different tracks. The DOJ case has completed fact discovery and started expert discovery. In this case, fact discovery has not yet even begun, and Ven-A-Care alone has suggested to Abbott that it wants to serve additional written discovery and take as many as twelve additional depositions in this case.

- This case will require additional fact discovery beyond that taken in the DOJ case. The DOJ case discovery was limited to four drugs that did not include Erythromycin, and although discovery in that case included some information that would be relevant here, new discovery focusing specifically on Erythromycin will be needed. One main example is claims data: The parties will have to round up data from all 50 states regarding provider numbers, dates of service, reimbursements paid, etc. It has taken the Department of Justice years to do this for the DOJ case even for its own Medicare data; even in that time, only 15-20 of the states have given individualized claim data.[6]

- Under the MDL rules, the DOJ case – which arose in Florida – will not be tried by this Court; this case, which arose with another judge in this District, will be transferred back to that Judge. Neither will be tried by this Court, let alone together.[7]

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[6] Moreover, as Ven-A-Care is very well aware from its attendance at depositions (including four of its own witnesses), Abbott's discovery efforts in DOJ case have focused extensively upon issues pertinent to the drug products at issue in that case. *See, e.g.*, B. Vladeck Dep. at 143-48, 169-78, 234-38 (former CMS Administrator); T. Scully Dep. at 186-193, 216-20, 341-77, 394-97, 416-27 (former CMS Administrator); C. Wiberg Dep. at 51-52, 79-124, 139-40, 171-89 (former Minnesota pharmacy director); L. Sullivan Dep. at 118-57, 190-93 (former Tennessee pharmacy director); M. J. Terrebonne at 32-35, 99-101, 173-81, 234-53 (Louisiana pharmacy director) (collected together as Ex. A.) These witnesses will have to be re-deposed regarding the separate issues that are distinctly pertinent to the drugs at issue in this case. As but just one example, Abbott has questioned several witnesses from the Centers for Medicare and Medicaid Services ("CMS") with respect to the lack of a Federal Upper Limit ("FUL") on the drugs at issue in the DOJ case. *See, e.g.*, T. Scully Dep. at 394-97, 416-20; S. Gaston Dep. at 118, 223-85, 315-38; L. Reed Dep. at 591-601, 838-43 (collected together as Ex. B.) By contrast, in this case, Ven-A-Care suggests that there *was* an FUL for Erythromycin. (Compl. ¶ 28.) As such, these and additional Government witnesses will have to be deposed regarding an entirely different and more detailed set of issues concerning the FUL program and its impact on the drugs in this case.

[7] Of course, Ven-A-Care's argument here also discredits its position that this case is so different from the first-filed DOJ case.

Thus, an interlocutory appeal would almost certainly be concluded far in advance of any final judgment that might ultimately be entered in this case even if discovery proceeded apace starting now. And, when the small wait that a stay would impose is weighed against the significant effort and expense to the Court and the parties that would be saved by a favorable appeal for Abbott, the balance falls heavily on the side of staying discovery. Besides, Ven-A-Care filed its first qui tam on the scheme alleged in this case in June 1995; after delaying litigation of these cases for over a decade, Ven-A-Care should not be heard to complain about a few more months' wait.

CONCLUSION

The motion should be granted. The Court should certify the March 14, 2008 order for interlocutory appeal, and should stay discovery while the First Circuit addresses this important and highly disputed matter.

Dated: May 9, 2008

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, David Torborg, an attorney, hereby certify that I caused a true and correct copy of the foregoing ABBOTT LABORATORIES' REPLY IN SUPPORT OF REQUEST FOR CERTIFICATION OF INTERLOCUTORY APPEAL UNDER 28 U.S.C. § 1292(B) AND STAY to be served on all counsel of record electronically by causing same to be posted via LexisNexis, this 9th day of May 2008.

/s/ David Torborg
David Torborg